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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,978	09/12/2000	Roger Hull	620-106	6992

7590 11/19/2002  
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8th Floor  
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Arlington, VA 22201-4714

EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

13

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/622,978

Applicant(s)

HULL ET AL.

Examiner

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 26 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4 and 6-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The Amendment filed August 26, 2002, paper no.12, has been entered.

Claims 5 and 20 are cancelled.

Claims 1-4, 6-8, 10-11, 13-14 and 18 are newly amended.

Claims 1-4 and 6-19 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

A substitute specification including the claims is still required pursuant to 37 CFR 1.125(a) because line 3 of each page is still too faint to be reproduced.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

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***Claim Rejections - 35 USC § 101***

The rejection of claims 10-12, 16-17 and 20 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in light of the amendment of claims 10-11.

***Claim Rejections - 35 USC § 112***

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "and a non-Banana Streak Virus sequence" is withdrawn in light of the amendment of claim 6.

Claims 1, 3-4 and 6-19 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the 5' region of an isolated polynucleotide consisting of SEQ ID NO:2 as an operably linked promoter for transcription of heterologous genes with said promoter, does not reasonably provide enablement for claims broadly drawn to other promoter sequences as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed March 26, 2002.

Applicant's arguments filed August 26, 2002, have been fully considered but they are not persuasive.

Applicant disagrees with the Examiner's assertion that the promoter function of sequences or sequence fragments of Badnavirus strains is unpredictable because strain

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differentiation is unpredictable, citing the high levels of sequence identity between RTBV variants, and arguing that a large sampling of quasispecies genomic structure would not be required to identify functional sequences (reply pages 7-8). Applicant also disagrees with the Examiner's assertion that chemical hybridization is unpredictable in identifying a Badnavirus species. Applicant points out that in the cited reference of Lockhart et al. (1993), while various techniques for virus typing were found to be unsuitable for BSV detection, a PCR based technique was used successfully. Regarding the hybridization conditions recited in the claims, Applicant argues that the entirely predictable process as hybridization under a specified set of conditions is dependent on the extent of complementarity between molecules, and that irrespective of the suitability of dot blot analysis for detecting BSV strains, chemical hybridization is an effective and predictable method for establishing the degree of relationship between nucleic acid molecules (reply pages 9-11).

The Examiner maintains that the ability of a promoter to function is directly dependent upon the sequence of the promoter, as the nucleotides of the promoter directly affect function through their specific interaction with regulatory proteins. Accordingly, even sequences that are highly homologous as a consequence of close phylogenetic relationship or highly stringent hybridization conditions may not exhibit promoter function because a change in as few as a single nucleotide can alter or eliminate promoter function.

Applicant additionally disagrees with the Examiner's assertion that the promoter function of the claimed polynucleotide is unpredictable for conferring expression in all plant cells and tissue types (reply pages 11-14).

Upon consideration of Applicant's arguments with respect to the promoter's ability to confer expression in plant cells other than *Musa*, the scope of enablement rejection has been modified to extend the scope of enablement to plant cells other than *Musa*.

Applicant finally disagrees with the Examiner's assertion that the specification does not provide guidance with respect to which bases of SEQ ID NO:2 may be altered without affecting promoter activity. Applicant argues that the present claims are directed to polynucleotides that are promoter sequences of isolates of BSV, and thus, while potentially being allelic variants of SEQ ID NO:2, the claimed promoter sequences are necessarily active, as a virus with an inactive promoter could not produce a successful infection from which isolates could be made. Applicant argues that the specification teaches those skilled in the art how to identify active sequence variants, and that one skilled in the art could obtain and use such promoters without any knowledge of which residues contribute to this activity. Applicant also argues that modification of residues and testing for activity would not be required, although such routine experimentation would be within the capability of one skilled in the art. Applicant argues that the claimed promoter sequence is structurally defined in terms of its source, its relationship to SEQ ID NO:2 and its function, and that the recited details are sufficient to define an active sequence without the necessity to recite additional features such as a specific length. Applicant argues that the specification discloses the materials necessary to practice the claimed invention, and provides guidance for expression in Musaceae cells and plants. Applicant argues that given the teachings of the specification, undue experimentation would not be required for one skilled in the art to

obtain and use active BSV promoter sequences that are allelic variants of SEQ ID NO:2 (reply pages 15-17).

The Examiner maintains that the specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which of the claimed polynucleotides would have promoter function. The claims are not limited to methods for obtaining and using active BSV promoter sequences that are allelic variants of SEQ ID NO:2, but are directed to the polynucleotide sequences themselves. The specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which of the claimed polynucleotides would have promoter function, because the specification discloses only a single polynucleotide that has promoter function, the polynucleotide of SEQ ID NO:2. The Examiner maintains that the undue experimentation lies in the process of selecting from among the many sequences claimed those polynucleotides that would be likely to have promoter function if subjected to a test for promoter function. In this respect the specification does not provide sufficient guidance for discriminating between functional and nonfunctional embodiments prior to testing for promoter function. Recitation in the claims that the sequences are isolates of BSV or that the sequences have promoter activity does not enable the claims as such assertions do not provide sufficient guidance for the recognition on the basis of structure of functional promoter sequences. Furthermore, definition of the claimed promoter in terms of its source, its relationship to SEQ ID NO:2 and its function is not sufficient to enable the scope of the claims, as the ability of a polynucleotide to function as a promoter is directly dependent on the number and nature of nucleotides in the promoter sequence.

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Claims 1 and 3-4 and 6-19 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed March 26, 2002.

Applicant's arguments filed August 26, 2002, have been fully considered but they are not persuasive.

Applicant argues that the specification indicates that the key feature of the claimed invention is a nucleic isolated from a BSV isolate that consists of SEQ ID NO:2, hybridizes to SEQ ID NO:2 under highly stringent conditions, or is at least 75% similar to SEQ ID NO:2, or a fragment thereof, that directs expression in one or more cells of a Musaceae plant (reply page 17). Applicant also argues that the BSV source of the promoter is a clear structural feature which distinguishes the sequence in the same way as the designation "mammalian" or "human". Applicant argues that the promoter sequence is defined in structural as well as functional terms, and that the claimed genus meets the written description requirements because it is defined in terms of what the promoter is as well as what it does (reply page 18). Applicant further argues that the prior art provides one skilled in the art access to all the means necessary to identify and obtain other species within the claimed genus (reply page 19).

The Examiner maintains that merely defining the claimed promoter in terms of some structural relationship to SEQ ID NO:2 by way of hybridization or sequence similarity coupled with the assertion that such sequences direct expression in one or more cells of a Musaceae plant does not meet the written description requirement. The Examiner further maintains that

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Applicant has described only one species of the claimed genus, the species of SEQ ID NO:2. Applicant has not described the structure of or characterized the function of any sequence that hybridizes to SEQ ID NO:2 under highly stringent conditions. Applicant has not described the structure of or characterized the function of any sequence at least 75% similar to SEQ ID NO:2. Applicant has not described the structure of or characterized the function of any sequence that is a fragment of SEQ ID NO:2. The Examiner additionally maintains that designation of the source of the sequence does not describe the sequence, whether such designation is "BSV" or "mammalian" or "human", as source designations neither structurally nor functionally describe a nucleotide sequence. Finally, the Examiner maintains that whether the prior art provides one skilled in the art access to all the means necessary to identify and obtain other species within the claimed genus is not germane to the written description requirement, as it is the Applicant who must describe a reasonable number of species in order to support the description of the claimed genus.

#### ***Claim Rejections - 35 USC § 102***

The rejection of claims 3-4 and 7 under 35 U.S.C. 102(b) as being anticipated by Lockhart et al. (1986, *Phytopathology*, Vol. 76, No. 10, pages 995-999) and Lockhart et al. (1993, pages 105-113, In: *Breeding banana and plantain for resistance to disease and pests*. CIRAD, Montpellier, France) is withdrawn upon further consideration and in view of the claim amendments. It is now considered that the references do not teach an isolated polynucleotide devoid of non-promoter sequences.

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The rejection of claim 1 under 35 U.S.C. 102(e) as being anticipated by Olszewski et al. (1999, US Patent No. 5,994,123 filed on August 9, 1996) in light of Lockhart et al. (1993, pages 105-113, In: Breeding banana and plantain for resistance to disease and pests. CIRAD, Montpellier, France) and Regenmortel et al. (2000, Virus Taxonomy: 7th Report of the International Committee on the Taxonomy of Viruses, Academic Press) is withdrawn in view of the claim amendments and Applicant's arguments that ScFV is not the same as BSV.

Claims 3-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Olszewski et al. (1999, US Patent No. 5,994,123 filed on August 9, 1996) in light of Lockhart et al. (1993, pages 105-113, In: Breeding banana and plantain for resistance to disease and pests. CIRAD, Montpellier, France) and Regenmortel et al. (2000, Virus Taxonomy: 7th Report of the International Committee on the Taxonomy of Viruses, Academic Press), for the reasons of record set forth in the office action mailed March 26, 2002.

Applicant's arguments filed August 26, 2002, have been fully considered but they are not persuasive.

Applicant's primary argument is that ScFV is not the same as BSV (reply pages 22-23).

Applicant's argument does not overcome the rejection of the claims for the following reasons. First, the claimed sequences do not specify a BSV source or percent similarity. Second, the recited stringency conditions appear to be moderate stringency conditions. Finally, even claim 4 in reciting "a nucleotide sequence found in a strain of Banana Streak Virus" doesn't recite the whole sequence, such that the sequence of claim 4 reads on as little as a "TATA" sequence.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Remarks***

Claim 2 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

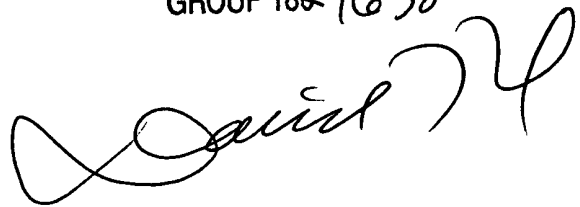
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
November 15, 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.